**~** 

@PFDesktop\::ODMA/MHODMA/INAK

PTO-1449 REPRODUCED ATTORNEY DOCKET NO. APPLICATION NO. 1733.1003-010 10/039,285 INFORMATION DISCLOSURE CITATION
IN AN APPLICATION
NAV 21, 2002 Howard Bernstein, et al. May 21, 2002 FILING DATE GROUP January 3, 2002 1615 (Use several sheets if necessary) U.S. PATENT DOCUMENTS FILING DATE SUB-EXAM-DOCUMENT NUMBER DATE NAME CLASS IF CLASS INER APPROPRIATE INI-TIAL 06/24/75 AA2 3,891,570 Fukushima, M. et al. 252 316 AB2 4,391,797 07/05/83 Folkman, M.J. et al. 424 19 AC2 5,176,907 01/05/93 Leong, K.W. 424 78.08 AD2 06/16/92 5,122,367 Ron, E. et al. 424 80 AE2 09/08/92 Lane, G.A. et al. 424 78.08 5,145,674 AF2 12/08/87 424 455 4,711,782 Okada, H. et al. AG2 06/30/92 Silvestri, L.J. et al. 497 5,126,147 424 AH2 5,192,741 03/09/93 Orsolini, P. et al. 514 4 AI2 4,732,889 03/22/88 Cynshi, O. et al. 514 8 AJ2 11/07/89 4,879,272 Shimoda, N. et al. 514 Я 4,992,419 02/12/91 Woog, H. et al. 514 8 FOREIGN PATENT DOCUMENTS SUB-TRANSLATION DOCUMENT NUMBER DATE COUNTRY CLASS CLASS YES NO AL2 W092/11844 23/7/92 per AM2 PCT WO W095/29664 A1 09/11/95 WO AN2 PCT-W094/12158 09/06/94 A02 0633 020 A1 11/01/95 **EPO** WO AP2 ₩093/1766B 16/09/93 Per AQ2 W094/07469 04/14/94 PCT OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Costantino, H.R., et al., "Aggregation of a Lyophilized Pharmaceutical Protein, Recombinant Human Albumin: Effect of Moisture and Stabilization by Excipients," Biotechnology, 13:493-496 (1995). Creighton, T.E., "Physical Forces That Determine the Properties of Proteins," In Proteins, Structures and Molecular Principles, (NY: W.H. Freeman and Company), pp. 149-150. S Cunningham, B. C., et al., "Dimerization of Human Growth Hormone by Zinc, " Science, 253:545-548 (August 1991). DATE CONSIDERED 03-31-2004

sheet 3 of 5 APPLICATION NO. ATTORNEY DOCKET NO. PTO-1449 REPRODUCED 10/039,285 1733.1003-010 TION DISCLUSION
IN AN APPLICATION INFORMATION DISCLOSURE CITATION APPLICANT Howard Bernstein, et al. May 21, 2002 FILING DATE GROUP January 3, 2002 1615 (Use several sheets if necessary) U.S. PATENT DOCUMENTS FILING DATE SUB-RXAM-CLASS CLASS DOCUMENT NUMBER NAME DATE INER APPROPRIATE TIAL 424 85.7 08/01/89 Yim, Z. et al. AA3 4,853,218 128 260 11/25/80 Theeuwes, F. AB3 4,235,236 Langer, R.S. et al. 03/06/90 424 428 AC3 4,906,474 424 497 AD3 5,019,400 5/28/91 Gombotz, W.R. et al. 424 486 Loomis, G.L. et al. 4,981,696 1/1/91 AE3 Gardner, D.L. 264 4.3 1/20/87 AF3 4,637,905 424 422 4,897,268 1/30/90 Tice, T.R. et al. AG3 424 426 Hutchinson, F.G. B/30/88 AH3 4,767,628 424 94 12/23/75 Briggs, A.R. et al. AI3 3,928,566 252 316 AJ3 4,166,800 9/4/79 Fong, J.W. Weissmann, C. 435 70 7/13/85 AK3 4,530,901 FOREIGN PATENT DOCUMENTS TRANSLATION CLASS COUNTRY DOCUMENT NUMBER DATE AL3 0580 428 AT 01/26/94 0537559 A1 21/04/93 **EPO** EMA 04/05/88 RPO 0266119 A3 AN3 0330180 A1 30/08/89 **EPO A03** WO 05/05/89 PCT AP3 W089/03678 жб90/13285 15/11/90 PET AQ3 WO OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Sato, Toyomi, et al., "Porous Biodegradable Microspheres for Controlled AΧ Drug Delivery. I. Assessment of Processing Conditions and Solvent Removal Techniques," Pharmaceutical Research, 5(1):21-29 (1988). Langer, R., "New Methods of Drug Delivery," Science, 249:1527-1533 (September 1990). Liu, W. R., et al., "Moisture-Induced Aggregation of Lyophilized Proteins in the Solid State, " Biotechnology and Bioengineering, 37:177-184 (1991). Lu, W., and Park, T. G., "Protein Release from Poly(lactic-co-glycolic acid). Microspheres: Protein Stability Problems, " PDA J. of Pharmaceutical Science & Technology, 49(1):13-19 (Jan-Feb 1995). DATE CONSIDERED 03-31-2004 TAMES M. SPEAR



Sheet 4 of 5

			/	7		Sheet 4 C	)			
PTO-1449 REPRODUCED 33				ATTORNEY DOCKET NO. 1733.1003-010	APPLICATION NO. 10/039,285					
7	infor	ATION DISCLOSURE C IN AN APPLICATION	NOITATI:	APPLICANT Howard Bernstein, et al			-1-			
		May 21, 2002		FILING DATE	GROUP					
	(Use	several sheets if nec	essary)	January 3, 2002	1615					
			υ.	S. PATENT DOCUMENTS						
BXAM- INBR INI- TIAL		DOCUMENT NUMBER	DATE	маме	CLASS	SUB- CLASS	FILING DATE IP APPROPRIATE			
Of	AA4	4,871,538	10/02/89	Yim, Z. et al.	424	85.7				
1	AB4	B1 4,985,404	04/21/92	Mitchell, J.W.	514/6	514/2				
	AC4	4,655,777	04/07/87	Dunn, R.L., et al.	623	16				
	'AD4	5,075,115	12/24/91	Brine, C.J.	424	486				
$\perp$	AE4	5,344,654	09/06/94	Rueger, D.C., et al.	424	423				
	AP4	4,237,114	12/02/80	Cardarelli, N.F.	424	78				
	AG4	4,806,524	02/21/89	Kawaguchi, T., et al.	514	8				
	AH4	4,252,791	02/24/81	Grossberg, S.E., et al.	424	85				
V	AI4	5,441,734	08/15/95	Reichert, P., et al.	424	85.7				
98	AJ4	5,413,797	05/09/95	Khan, M.A., et al.	424	489				
	AK4					<u></u>				
			FORE	IGN PATENT DOCUMENTS	•	<b>.</b>	·			
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO			
98	AL4	0 595 030 A2	05/09/91	per WO						
外	AM4	ы <b>093/02712</b>	18/02/93	per WO						
	AN4	W095/11010	27/04/95	pet WO						
	AO4	Ж094/19373 A1	01/09/94	PCT WO						
V	AP4	0 307 097 A2	15/03/89	EPO						
98	AQ4	₩Ø91/18927 A1	12/12/91	per WO						
		OTHER DOCUMENT	S (Including	Author, Title, Date, Pertinen	t Pages,	Btc.)	<del> </del>			
98	A\$2	Cohen, S., et al., "Controlled Delivery Systems for Proteins Based on Poly(Lactic/Glycolic Acid) Microspheres," Pharmaceutical Research, 8(6):713-720 (1991).								
88	AT2	Hora, M.S. et al., "Release of Human Serum Albumin from Poly(lactide-co-glycolide) Microspheres," Pharmaceutical Research, 7(11):1190-1194 (1990).								
98	AU2	Hageman, M.J., et al., "Preformulation Studies Oriented Toward Sustained Delivery of Recombinant Somatotropins," J. Agric. Food Chem., 40:348-355 (1992).								
EXAMIN	ier 7 M	ES M. SI	PEAR	DATE CONSIDERED  03-34-20	004					

~					-					
PTO-1849 REPRODUCED MAY 2 8 2002				ATTORNEY DOCKET NO. 1733.1003-010		APPLICATION NO. 10/039,285				
	INPOF	MATION DISCLOSURE CO IN AN APPLICATION	TATION S	APPLICANT Howard Bernstein, et	al.					
	(IIse	May 21, 2002 several sheets if nece	FILING DATE January 3, 2002	GROUP 1615						
<del></del>				PATENT DOCUMENTS			<del></del>		<u> </u>	
EXAM-					Τ		SUB-	FILING	DATE	
INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS CLAS		CLASS			
					<u> </u>			ļ		
<del></del>					<u> </u>			<u> </u>		
					1. 1					
			. //		<u> </u>			<u> </u>		
FOREIGN PATENT DOCUMENTS										
		DOCUMENT NUMBER	DATE	COUNTRY	CIM	ea	SUB- CLASS	TRANSLI YES	NOITA ON	
98	AL5	0 123 291 A2	31/10/84	EPO						
外	AM5	0 281 299 A1	07/09/88	EPO						
.]/	AN5	0 251 680 A2	07/01/88	EPO						
93	105	жб92/19226	12/11/92	DOW WO		/				
$\overline{U}$		OTHER DOCUMENTS	(Including Au	thor, Title, Date, Pertinen	t Pag	es,	Stc.)			
98	AV2	Cleland, J. L., et al., "Characterization of Recombinant Human Growth Hormone-PLGA Formulations in Animals," Proceed, Intern. Symp. Control. Rel. Bioact. Mater., 22:143-144 (1995).								
	AW2	Cleland, J. L., et al., "One Month Continuous Release Recombinant Human Growth Hormone-PLGA Formulations," Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 22:149-150 (1995).								
	AX2	Mullerad, J., et al., "Delivery of IL-1 Microspheres to Tumor Macrophages," Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 22:512-513 (1995).								
	AX2	Cleland, J. L., et al., "In Vitro Release of Bioactive Recombinant Human Interferon-y From PLGA Microspheres," Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 22:518-519 (1995).								
	AR2	Park, T. G., et al., "Importance of In Vitro Experimental Conditions on Protein Release Kinetics, Stability and Polymer Degradation in Protein Encapsulated Poly(D.:-Lactic Acid-Co-Glycolic Acid) Microspheres, " J. of Controlled Release, 33:211-222 (1995).								
	AS2	Nagata, S., et al., "Synthesis in E. Coli of a Polypeptide with Human Leukocyte Interferon Activity," Nature, 284:316-320 (March 1980).								
V	AT2	Rubinstein, M., "The Structure of Human Interferons," Biochimica et Biophysica Acta., 695:5-16 (1982).								
Z	AU2 Sah, H., et al., "The Influence of Biodegradable Microcapsule Formulations on the Controlled Release of a Protein," J. of Controlled Release 30:201-211 (1994).									
JAMES M. SPEAR DATE CONSIDERED 03-31-2004										